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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,081	07/24/2002	Michael Cawthorne	0380-P02819USO	7287

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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,081	CAWTHORNE ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,25-36,40-45 and 48-59* is/are pending in the application.

4a) Of the above claim(s) *2-23,25-27,40-45,48,53,54,58 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,28-36,49-52 and 55-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23,25-36,40-45 and 48-59* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 24, 37-39, and 46-47 have been cancelled.

Election/Restrictions

Applicant's election with traverse of Group I, with requirements A-E, in the reply filed on 2/10/06 is acknowledged. The traversal is on the ground(s) that the restriction and species election is onerous and unwarranted and doesn't comply with the requirements for lack of unity. This is not found persuasive because the claims embrace many different embodiments from the perspective of medical condition, genetic mutations, animals, differentially expressed proteins and their resulting combinations.

Applicant is reminded that lack of unity is present where no special technical feature exists. If art can be applied against the first claim, then no special technical feature is present and there is lack of unity.

Anderson et al. (Ref. C12, Diabetes, 44:401-407, April 1995) discloses differential expression of proteins by two-dimensional gel eletrophoresis of rat islet proteins following administration of interleukin-1β or nicotinamide. This reference meets all of the limitations of claim 1.

See also Edvardsson et al. (Ref. C14) which discloses a proteomics analysis of livers from obese (ob/ob) mice treated with agonists and Sanchez (Ref. C15) which discloses proteomic studies in obesity and NIDDM by administering rosiglitazone. These references also meet all of the limitations of claim 1.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election for requirements A-E is problematic because they are internally inconsistent. For example, selecting ob/ob mice for the genetic mutation is excludes sand rats as the animal. In addition, the combination of elements elected has no basis in the specification as a contemplated embodiment and therefore any claim directed to this combination of limitations would be considered new matter.

The examiner has interpreted applicant's election, the specification disclosure, and the claims to the best of her ability and examined the following method with respect to art and enablement.

A method of screening an agent to determine its usefulness in treating obesity, the method comprising:

obtaining a sample of muscle tissue taken from an ob/ob mouse which has been treated with the agent being screened,

determining the presence, absence or degree of expression of the protein MOM34, and

selecting or rejecting the agent according to the extent to which it changes the expression of the MOM34 protein in said ob/ob mouse.

This method appears to be in keeping with what the specification discloses and what applicant elected. Note that the paradigm of claim 1 is implicitly the methodology of Example 2, starting at page 96 of the specification, where MOM34 was identified. Applicant is advised that the above claim language should not be construed as an invitation to add a claim with this particular language or set of steps. Any future amendments applicant makes to the claims must be supported by the originally filed specification and basis should be pointed out.

The following claims appear to correspond to this method and the protein of interest: 1, 28-36, 49-52, and 55-57. Note only MOM34 has been considered.

Claims 2-23, 25-27, 40-45, 48, 53-54, and 58-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/10/06.

Claim Rejections - 35 USC § 112

Claims 1, 28-34, 36, and 55-57 are not rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claim 1 has been interpreted as set forth above.

Example 2 of the specification discloses that gastrocnemius muscle tissue from non-fasted lean and obese C57 B1/6J ob/ob mice differentially express MOM34 protein. Page 97 identifies the MOM34 protein as an IRP2 or iron responsive element binding protein 2 having the SWISS-PROT accession number Q62751. Page 96 discloses that MOM34 was underexpressed in ob/ob skeletal muscle relative to lean mouse skeletal muscle.

The specification does not disclose differential expression of the MOM34 protein in any other mouse model, in any other tissue from these mice, or in any other animal. The

specification does not administer any agent to these mice and does not show any change in expression of the MOM34 protein in response to administration of the agent.

The congenic C57B1/6J ob/ob strain would have been a well known mouse model of obesity. See Zhang et al. (Nature, 372:425-43, 1994). These mice have a recessive mutation and are morbidly obese. The gene responsible for this phenotype has been identified and characterized. Note that the claims are not limited to paradigms using established or well characterized inbred animal models that are genetically homogenous and paradigms where environmental factors such as dietary intake can be tightly controlled for valid comparisons.

Guo et al. (Journal of Biological Chemistry, 270(28):16529-16535, 1995) characterize and express iron regulatory protein 2 (IRP2). This reference corresponds to SWISS-PROT accession number Q62751. Guo et al. do not disclose any association of this protein or its activity with obesity. In fact, targeted delection of this gene causes misregulation of iron metabolism and neurodegenerative disease in mice. There is no disclosure of any obesity related effects when this gene is deleted. (See La Vaute et al., Nature Genetics, 27:209-214, 2001.)

In view of the above information, one of ordinary skill in the art would have reason to doubt that a change in expression of IRP2 in response to any agent would correspond in any way to that agent's usefulness in treating obesity. One of ordinary skill in the art would not have believed that changes in IRP2 levels would cause or ameliorate obesity. One of ordinary skill in the art would not have believed that agents that modulated IRP2 levels would be useful in treating obesity.

It is noted that the examiner found no association in the subsequent or prior art between administration of leptin and IRP2.

It is noted that the specification does not appear to disclose any paradigm that does not involve two-dimensional gel electrophoresis for determining differential protein expression.

For all of these reasons, the claims are not enabled.

Claims 29-33 and 55-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is confusing in adding the step of isolating the differentially expressed protein and claim 30 is confusing in adding the step of further characterizing the protein. These steps do not make clear how they further limit the method of screening the agent to determine its usefulness. Claims 32-33 and 55-57 are similarly unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-36 and 49-52 are rejected under 35 U.S.C. 102(b) as being antipated by Guo et al. (Journal of Biological Chemistry, 270(28):16529-16535, 1995).

Guo et al. characterize and express iron regulatory protein 2 (IRP2). The mouse protein is disclosed as isolated and present in a composition. See at least page 16533, right column, through page16534, left column and Figures 6 and 7.

Applicant is reminded that a product is examined as a product irrespective of how it is identified or isolated. (See for example, claim 35 "after having identified an agent using the method of claim 1" and the isolation steps set forth in claim 49) Intended uses are given no patentable weight in a product claim. (See for example claim 36 "for use in a method of medical treatment.") With respect to claims 51 and 52, IRP2 has a pI and MW because these are properties of all proteins.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne P. Allen
Primary Examiner
Art Unit 1647

mpa